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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,752	03/09/2001	Gerhard Schmidmaier	8932-148	8071

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/801,752	SCHMIDMAIER ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-31 and 60-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-31 and 60-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Change of Correspondence Address, the Amendment and Applicant's Arguments/Remarks, all filed 09/15/04 is acknowledged.

Claims 1-6, 8-31 and 60-63 are pending. Claim 1 has been amended. Claim 7 has been cancelled. New claims 60-63 have been added. Claims 32-59 have previously been withdrawn. Claims 1-6, 8-31 and 60-63 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 8-19 and 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arm *et al.* (WO 93/20859).

Arm *et al.* teach implants and prosthetic devices having an outer surface coated with biodegradable polymeric films, which comprise polylactic acid/polyglycolic acid copolymers, therapeutically effective amounts of growth factors, active agents and carriers, wherein the polymeric films have a preferred thicknesses of less than about 50 microns. The films may be affixed to the outer surface of the implant or prosthetic device, which include a screw, pin, plate, rod or artificial joint component. The films and rods are therapeutically useful for promoting tissue growth and repair, particularly for enhancing repair of bone fractures (see page 3 line 32 through page 7, line 10) and abstract and claims.

According to Arm, degradation of the film and consequent release of growth factors therefrom can be modulated by adjusting such film parameters as molecular weight, copolymer structure, copolymer ratio and thickness. In general, the film will be formulated using a copolymer having a molecular weight between 10,000 and 200,000 Daltons. Film thicknesses of less than about 50 microns are preferred. Figure 1 illustrates a 40-50 micron film of PLA/PGA random copolymer of approximately 100,000 molecular weight (page 6, line 28 through page 7, line 5).

Suitable polypeptide growth factors include PDGF, TGF-alpha, TGF-beta, IGF-I, bFGF, aFGF, EGF and the like. Growth factors may be used singly or in combination with one another (page 7, line 6-17). Suitable biodegradable polyester films include polylactic acid, polyglycolic acid, polydioxanone or polylactic acid/polyglycolic acid copolymer films (page 5, lines 10-19).

In addition to the copolymers, growth factors and carriers, the biodegradable films may include other active or inert components. Of particular interest are those agents that promote tissue growth or infiltration. Agents that promote bone growth, such as morphogenic proteins, osteogenin and NaF, for example can be included (page 11, line 32 through page 12, line 4).

Regarding the amount of polymer employed per ml of solvent, Arm in Example 1, page 15, demonstrates the teaching of polylactic acid and polylactic acid-polyglycolic acid films that were solvent cast by dissolving approximately 340 mg of polymer granules in 10 ml of chloroform at room temperature and allowing the solvent to evaporate completely in an air hood.

With respect to the instant percentages (0.1-10%) and instant combinations of growth factor, it appears that the amounts taught by Arm (0.0375 and 1.5 micrograms per mg of copolymer – pg 12, lines 13-24) fall within the applicant's claimed ranges. Furthermore, one of ordinary skill in the art could determine suitable ranges through routine or manipulative experimentation to obtain the best possible results. There is no criticality seen in the amounts of growth factor employed since Arm explicitly teaches similar amounts for a similarly intended purpose. Furthermore, there is no criticality seen in the particular combination of growth factors, since Arm clearly suggests at page 7, lines 8-10, that the growth factors may be used singly or in combination. One of ordinary skill would select a suitable growth factor or a combination of growth factors, based on the intended purpose at hand.

Claims 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arm *et al.* (WO 93/20859) in view of Bates *et al.* (US Pat. No. 6,530,951 B1).

Arm *et al.,* as delineated above, teach implants and prosthetic devices having an outer surface coated with biodegradable polymeric films, which comprise polylactic acid/polyglycolic acid copolymers, therapeutically effective amounts of growth factors, active agents and carriers, wherein the polymeric films have a preferred thicknesses of less than about 50 microns. The films may be affixed to the outer surface of the implant or prosthetic device, which include a screw, pin, plate, rod or artificial joint component. The films and rods are therapeutically useful for promoting tissue growth and repair, particularly for enhancing repair of bone fractures (see page 3 line 32 through page 7, line 10) and abstract and claims.

Arm *et al.* do not teach a base material that is *not* biodegradable.

Bates *et al.* teach an implantable medical device comprising a base material that may be either biodegradable or *non*-biodegradable. The base material can be at least one of stainless steel, titanium, gold, platinum, silver or another biocompatible metal, or alloys of any of these (see reference column 9, lines 30-58).

It would have been obvious to one of ordinary skill in the art to employ either the biodegradable or non-biodegradable implant base materials of Bates *et al.* within the implant of Arm *et al.* if the intended purpose was to obtain base materials that alter their physiochemical states (*i.e.*, biodegradable) or those base materials that do not alter their physiochemical states (*i.e.,* non-biodegradable). The expected result would be an effective implant for the treatment of various medical conditions.

Claims 1, 2, 4, 5, 8-10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eitenmuller *et al.* (US Pat. No. 4,610,692).

Eitenmuller *et al.* teach an implant for filling bone cavities and fixing bone fragments in a living body comprising at least one coating of predetermined thickness, about 4 microns to about 30 microns, of a biodegradable substance selected from at least one of polymethacrylate, polylactide, polydextran and cellulose-based substances, wherein the implant also comprises at least one therapeutically active ingredient (see reference column 3, line 10 through col. 4, line 36); (col. 6, lines 14-25); (col. 7, lines 23-44); and claims.

Claims 1-6, 8-12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Healy *et al.* (US Pat. No. 5,670,161).

Healy teach an expandable, biodegradable stent for use within a body lumen comprising a hollow tube made from a copolymer of L-lactide and caprolactone, wherein the stent incorporates surface coatings or thin films having a thickness of about 25 microns and whereby suitable polymers include polyethylene glycol, polyvinyl alcohol, polyvinyl pyrrolidone, polymethacrylic acid and polyacrylamide that are blended and copolymerized with biodegradable materials. The film may coat only surfaces of the stent or may extend over the micro-machined perforations in the stent. The stent may also desirably incorporate one or more drugs, growth factors and inhibitors (see reference column 5, lines 27-60); (col. 10, lines 10-48); and claims.

Response to Arguments

Applicant's arguments filed 09/15/04 have been fully considered but they are not persuasive.

Firstly, Applicant argued regarding the rejection of claims 1-5, 7-19 and 21-31 under 35 U.S.C. §103(a) over Arm et al. stating, "The Arm PCT Application is directed to a biodegradable film which can be affixed to an implantable or prosthetic device. The Arm application does not expressly describe what is meant by 'affixed'. Arm does not teach or suggest an implant coated with a varnish-like polymer, let alone a polymer that forms an adhesive bond to the surface of the implant. Arm teaches implants that are wrapped by a preformed film."

These arguments have been fully considered, but were not found to be persuasive. Arm teaches an implant wherein the biodegradable film is affixed to the outer surface of the implant (see pg. 4, lines 12-25). Applicants' argument that Arm does not teach a varnish-like polymer is unpersuasive since Arm teaches the same polymeric films, such as those desired by Applicants, such as polylactic acid, polyglycolic acid and the like. Applicant's attempt to distinguish over the polymers by utilizing the term 'varnish-like', however, the polymers taught by Arm and those instantly claimed are, in essence, the same polymers, regardless of the term used. Applicant's argument that Arm 'do not teach a polymer that forms an adhesive bond to the surface of the implant' is also not persuasive because Arm explicitly teaches that the films are 'affixed' to the implant. The term "affixed" as defined in *Merriam Webster's Collegiate Dictionary (10th ed.)*, is defined as "to attach physically (i.e., a stamp to a letter). Therefore, the affixation of the polymeric film to the implant in Arm, would be considered as being attached with sufficient strength to form a bond, whether chemical or physical. Applicants have not

demonstrated any significant distinction between the 'adhesive bond' instantly claimed and the affixation taught by the prior art. The prior art clearly teaches and acknowledges implants comprising films, such as those claimed that are physically affixed to the surfaces of the implant.

Secondly, Applicant argued regarding the rejection of claims 1, 2, 4, 5, 8-10 and 20 under 35 U.S.C. §103(a) over Eitenmuller stating, "Eitenmuller does not teach or suggest a coating containing a biodegradable polymer, where the biodegradable polymer has a mean molecular weight of 100 kDa or less, as recited in amended claim 1."

This argument has been fully considered, but was not persuasive. Although Eitenmuller does not explicitly teach the instantly claimed mean molecular weight, the Examiner points out that, generally, differences in molecular weights, will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such molecular weight is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Eitenmuller teach an implant comprising a predetermined thickness coating and teach various biodegradable substances and therapeutically active ingredients in the implant. One of ordinary skill familiar with this art could readily determine suitable molecular weights through routine or manipulative experimentation to obtain optimal results, as molecular weights are indeed variable parameters within the art

Next, Applicant argued with regards to the rejection of claims 1-6, 8-12 and 20 over Healy stating, "Healy does not teach or suggest a coating containing a biodegradable polymer, where the biodegradable polymer has a mean molecular weight of 100 kDa or less, as recited in amended claim 1".

This argument was not persuasive since Applicants have not demonstrated any unusual and/or unexpected results attributable to the instantly claimed molecular weight range. A skilled artisan within the art could determine suitable amounts.

Lastly, Applicant stated that new claim 60 is directed to an implant comprising a base material that is not biodegradable. Applicant states that "neither Arm, nor Eitenmuller nor Healy teach or suggest an implant comprising a base material that is not biodegradable."

This argument was not persuasive. New claims 60-63 have been rejected over Arm *et al.* ('859) in view of Bates *et al.* ('951). The teachings of Arm *et al.* are delineated above. Arm *et al.* do not explicitly teach non-biodegradable polymer films. Bates *et al.* is relied upon to remedy this deficiency of Arm *et al.*, by explicitly teaching implants comprising base materials that are either biodegradable or *non*-biodegradable. Suitable base materials include stainless steel, titanium, gold, platinum, silver or other biocompatible metals, or alloys of any of these (see Bates *et al.* column 9, lines 30-58). The prior art clearly teaches medical implants incorporating the same components, used for the same field of endeavor and to treat the same problems, as that desired by Applicants. Therefore, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh H.N.S.

Patent Examiner

Art Unit 1615

December 23, 2004

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